



DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS-2018-0007]

RIN 0579-AE73

Importation of Fresh Beef From Paraguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products by allowing, under certain conditions, the importation of fresh (chilled or frozen) beef from Paraguay. Based on the evidence from a risk analysis, we have determined that fresh beef can safely be imported from Paraguay, provided certain conditions are met. This final rule will provide for the importation of fresh beef from Paraguay into the United States, while continuing to protect the United States against the introduction of foot-and-mouth disease.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Dr. Ingrid Kotowski, Import Risk Analyst, Regionalization Evaluation Services, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855-7732; AskRegionalization@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including foot-and-mouth disease (FMD), African swine

fever, classical swine fever, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Under most circumstances, § 94.1 of the regulations prohibits the importation of live ruminants and swine and fresh (chilled or frozen) meat derived from ruminants and swine originating in, or transiting through, a region where FMD exists. Section 94.11 restricts the importation of ruminants and swine and their meat and certain other products from regions that are declared free of FMD but that nonetheless present a disease risk because of the regions' proximity to or trading relationships with regions affected with FMD. Regions that the Animal and Plant Health Inspection Service (APHIS) has declared free of FMD and regions declared free of FMD that are subject to the restrictions in § 94.11 are listed on the APHIS website at <https://www.aphis.usda.gov/animalhealth/disease-status-of-regions>.

The regulations do allow for certain exceptions to the prohibitions contained in § 94.1. These exceptions include allowing the importation of fresh (chilled or frozen) beef and ovine meat from Uruguay and fresh beef from certain regions of Argentina and a region of Brazil, subject to certain conditions. While there have been FMD outbreaks in the past in those regions, the disease is not currently known to exist in any of them. We do not recognize those exporting regions as FMD-free, however, because the Argentine, Brazilian, and Uruguayan governments all require that cattle be vaccinated for FMD. The conditions for the importation of beef and ovine meat from Uruguay and beef from the exporting regions of Argentina and Brazil are set out in § 94.29 of the regulations and include the following:

- The meat is derived from animals born, raised, and slaughtered in the exporting region.
- FMD has not been diagnosed in the exporting region within the previous 12 months.
- The meat comes from bovines or sheep that originated from premises where FMD has not been present during the lifetime of any bovines and sheep slaughtered for the export of meat to the United States.

- The meat comes from bovines or sheep that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
- The meat comes from bovines or sheep that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.
- The meat consists only of bovine parts or ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter and before removal of any bone, blood clots, or lymphoid tissue. The bovine and ovine parts that may not be imported include all parts of the head, feet, hump, hooves, and internal organs.
- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat to be exported (bone-in ovine meat from Uruguay may be imported under certain conditions listed in the regulations, however).
- The meat has not been in contact with meat from regions other than those listed in accordance with § 94.1(a).
- The meat came from carcasses that were allowed to mature at 40 to 50 °F (4 to 10 °C) for a minimum of 24 hours after slaughter and that reached a pH below 6.0 in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both longissimus dorsi muscles. Any carcass in which the pH does not reach less than 6.0 may be allowed to mature an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States.
- An authorized veterinary official of the government of the exporting region certifies on the foreign meat inspection certificate that the above conditions have been met.

- The establishment in which the bovines and sheep are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

Historically, trade in fresh (chilled or frozen) beef from Paraguay has not been allowed because APHIS has considered Paraguay to be a country that vaccinates for FMD. However, in response to a request from the Government of Paraguay that we allow fresh (chilled or frozen) beef to be imported into the United States from that country, we conducted a risk analysis. APHIS gathered data to support this analysis from records of the Servicio Nacional de Calidad y Salud Animal (SENACSA), from publicly available information, and from published scientific literature. In addition, APHIS conducted site visits to Paraguay in December 2008 and July 2014 to verify the information submitted by SENACSA and to collect additional data. APHIS drafted the risk analysis in 2018 and periodically reviewed the risk profile of Paraguay to determine whether the conclusions were still valid, with the last such review occurring in 2022.

Our risk analysis concluded that the overall risk associated with importing fresh beef from Paraguay is low and that Paraguay has the infrastructure and emergency response capabilities needed to effectively report, contain, and eradicate FMD in the event of an outbreak and to do so in a timely manner. We further concluded that Paraguay is able to comply with U.S. import restrictions on the specific products from affected areas.

Based on the evidence documented in our risk analysis, we concluded that fresh (chilled or frozen) beef could be safely imported from Paraguay, provided certain conditions are met.

Accordingly, on March 27, 2023, we published in the *Federal Register* (88 FR 18077-18086, Docket No. APHIS-2018-0007) a proposal¹ to amend the regulations to allow the importation of fresh beef from Paraguay under certain conditions.

¹ To view the proposed rule, supporting documentation, and comments that we received, go to <https://www.regulations.gov/docket/APHIS-2018-0007>.

We solicited comments concerning our proposal for 60 days, ending May 26, 2023. We received 152 comments by that date. They were from producers, importers, exporters, industry and professional associations, and representatives of local and foreign governments. Thirty-two commenters were generally supportive of the proposed rule. The remaining commenters raised questions or concerns about the proposed rule and the risk analysis. The comments are discussed below.

General Comments

One commenter stated that the rule is antithetical to the United States Department of Agriculture's (USDA's) statutory directive to "strengthen [America's] family farm system" (7 U.S.C. 2204).

The statute in question directs the Secretary of Agriculture to "advise the President, other members of his Cabinet, and the Congress on policies and programs designed to improve the quality of life for people living in the rural and nonmetropolitan regions" of the United States, and authorizes the Secretary to initiate or expand research and development efforts related to solution of problems the Secretary may determine has an effect upon the economic development or the quality of life in rural areas, among other stated duties. It does not represent an overriding ministerial obligation. This rulemaking was issued pursuant to a different statute, the Animal Health Protection Act (AHPA, 7 U.S.C. 8301-8317), which is not mutually contradictory with the statute cited by the commenter.

One commenter stated that the rule is being driven by World Trade Organization (WTO) commitments, rather than AHPA obligations. The commenter cited a statement from the environmental assessment (EA) that was issued in support of the proposed rule as evidence of this, and stated that this is the sole statement made in the proposed rule or its supporting documents regarding the impetus for the rule. Similarly, a commenter stated that the proposed rule is driven by the APHIS 2022 Strategic Plan (goal # 4) as an effort to facilitate international trade and open up markets.

The United States is a member of the WTO and a co-signatory to the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which governs, among other things, international trade in animal products.² Additionally, the commenter is correct that goal # 4 of APHIS' Strategic Plan is trade-related: To maintain and expand the safe trade of agricultural products nationally and internationally.³

APHIS is committed to upholding the principles of the SPS Agreement. The statement from the EA cited by the commenter acknowledges this, and states that the analyses conducted in support of the rule adhered to these principles. Additionally, a stated purpose of the APHIS Strategic Plan is to "outline the goals, objectives, and performance measures that set the direction" for APHIS in the coming years.

However, neither the SPS Agreement nor the APHIS Strategic Plan prompted the proposed rule. Rather, the proposed rule was driven by Paraguay's request to export fresh beef to the United States and subsequently APHIS' evaluation of that request. Based on a risk analysis, APHIS determined that fresh beef can be imported from Paraguay under certain conditions. These include verifying FMD has not been diagnosed in Paraguay in the past 12 months, the meat comes from premises where FMD has not been present during the lifetime of any of the animals, and the animals were inspected before and after death, among others. Authorizing the importation of animal products subject to mitigations to address the disease risk to livestock that the products may otherwise present is entirely consistent with the AHPA, the authority under which the proposed rule was issued. Finally, contrary to the first commenter's assertion, this was stated repeatedly in the proposed rule and its supporting documents.

One commenter stated that APHIS' risk factors used for evaluating countries, which the commenter stated undergird our risk analyses relative to FMD, were developed to meet WTO obligations and World Organization for Animal Health (WOAH) commitments rather than

² To view the SPS Agreement, go to https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

³ To view the APHIS Strategic Plan, go to https://www.aphis.usda.gov/aphis/banner/aboutaphis/sa_overview/ct_about_aphis.

AHPA obligations and do not mitigate risk. Additionally, the commenter stated that, in the past, APHIS miscalculated the FMD risk of importing beef from multiple countries (Argentina, Japan, South Africa, and South Korea) using these factors. The commenter pointed to outbreaks of FMD in the countries in question shortly after our evaluations. The commenter indicated that, based on previous experience, the risk factors should not be used for evaluations of a region's FMD risk.

The commenter appears to be referring to the provisions of paragraph (b) of 9 CFR 92.2. Under those provisions, requests for APHIS recognition of animal health status of a region must include the following eight categories of information, or factors:

- Scope of the evaluation being requested.
- Veterinary control and oversight.
- Disease history and vaccination practices.
- Livestock demographics and traceability.
- Epidemiological separation from potential sources of infection.
- Surveillance.
- Diagnostic laboratory capabilities.
- Emergency preparedness and response.

The factors are used to analyze the risk for import requests and not intended to have mitigative effect or to specify final agency action. We use this framework of eight information categories (or “factors”) to ensure consistent and thorough information gathering for our analysis of a region's health status.

One of the factors, emergency preparedness and response, includes an assessment of the ability of the foreign region to quickly detect and contain disease incursions and to promptly notify the United States and other trading partners of such incursions. This factor is germane in the event of an outbreak in the region. To that end, APHIS routinely monitors the international animal health situation, and as import risk levels change over time, APHIS adjusts its import

requirements as necessary. In other words, the factors facilitate actively monitoring the disease status of our trading partners and taking appropriate action, as warranted, if the disease status changes.

The effectiveness of this approach, supported by robust, science-based import risk assessments, rigorous APHIS import regulations, and APHIS' ability to take immediate trade-restrictive action when needed, is demonstrated by the continued FMD freedom of the United States. The effectiveness of the approach is also underscored, rather than undercut, by the examples that the commenter cites regarding importation of beef from Argentina, Japan, South Africa, and South Korea. Incursions of FMD into those countries were rapidly detected and communicated to trading partners, and APHIS accordingly promptly restricted importation of relevant animal commodities. Moreover, the incursion of FMD into the countries is not indicative of a failure in our evaluations, as the evaluations never reached a conclusion that FMD could not be introduced into the countries in question.

One commenter stated that Paraguayan husbandry and on-farm practices were not assessed. Others stated that Paraguayan producers may be allowed to use vaccines, biologics, parasite controls, or growth hormones that are banned in the United States.

We conducted multiple evaluations through on-farm inspections during APHIS site visits and detailed review of relevant documentation. Additionally, during the risk analysis, APHIS evaluated animal husbandry and on-farm practices in Paraguay. Our risk analysis evaluated Paraguay's request in a manner consistent with our statutory authority, which pertains to pests and diseases of livestock, and determined that fresh beef can be safely imported from Paraguay under certain conditions, which were set forth in the proposed rule as regulatory requirements. With that being said, USDA's Food Safety and Inspection Service (FSIS) and the Food and Drug Administration evaluate beef imports for the possible human health risks mentioned by the commenter.

Two commenters stated that imports should only be authorized from countries with the same food safety regulations and animal husbandry practices as our own, because otherwise Paraguayan producers are given an unfair competitive advantage over U.S. producers that have to abide by U.S. food safety regulations and animal husbandry practices. One of the commenters was also concerned about Paraguayan beef being contaminated as a result of not being listed by the U.S. Anti-Doping Agency as having tighter regulations and higher quality standards for its meats.

FSIS is entrusted with making sure the food safety regulations of other countries are equivalent to those of the United States. With regard to animal husbandry and on-farm practices, under the Animal Health Protection Act, APHIS may prohibit or restrict imports only to the extent necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. We assess the risk of the importation of animals, animal products, and other articles from countries based, in part, on their own practices, and identify appropriate mitigations based on this assessment of risk.

A commenter stated that the rule will hasten deforestation in Paraguay and cited three articles in support of this comment.

While one of the articles cited by the commenter does correlate beef exports from the Chaco region of Paraguay to an increased risk of deforestation, the article does not provide the data that led to this conclusion and also indicates that other beef-producing municipalities in Paraguay do not share this risk. Moreover, the other articles cited by the commenter cite multiple factors leading to deforestation in the Chaco region, including increased planting of soy and other crops, increased demand within Paraguay for beef and leather, producers' unlawful appropriation of land for personal gain, and changing climatic conditions. The articles provide no direct evidence that this rulemaking specifically will hasten deforestation in Paraguay.

Several commenters stated that FMD was a high-risk disease, and that APHIS failed to characterize the current risk of introduction of FMD into the United States or the cumulative effect of authorizing additional imports from a country that vaccinates for FMD.

We agree that FMD is a high-risk disease; however, neither the proposed rule nor its supporting documentation characterized it otherwise.

With regard to characterizing the current risk of introduction of FMD into the United States or the cumulative effect of authorizing additional imports from a country that vaccinates for FMD, the commenter misunderstands how APHIS assesses FMD risk. APHIS looks at each market access request as a distinct request, and tailors mitigations based on the unique circumstances of the exporting country, which may or may not be commensurate with previously evaluated countries. We do not authorize imports unless we believe the disease risk of that import can be adequately mitigated.

One commenter stated that APHIS should only authorize trade if it presents zero risk of transmitting diseases of livestock.

All trade, whether domestic or international, involves a degree of risk, however miniscule. The commenter's request would have the effect of a de facto prohibition on the importation and interstate movement of livestock and animal products.

Finally, several commenters stated that the rule needed to include country-of-origin labeling, or COOL.

In 2015, Congress repealed the legislation authorizing the Executive branch to implement COOL for muscle cuts of beef and pork and ground beef and pork.⁴ Moreover, COOL has never been administered by APHIS within the USDA, but by the USDA's Agricultural Marketing Service.

Risk Analysis Comments

⁴ To view the statute containing the Congressional repeal of COOL, go to <https://www.congress.gov/bill/114th-congress/house-bill/2029/text>.

As noted previously, the proposed rule was based on a risk analysis that we prepared regarding Paraguay's export request. We received several comments concerning the risk analysis.

One commenter stated that, in 2017, the Government Accountability Office (GAO) conducted an audit of APHIS' risk analysis practices and indicated areas for improvement with APHIS' risk evaluations in terms of timeliness and transparency. The commenter stated that the Paraguay evaluation appeared to have been conducted before APHIS implemented GAO's recommendations.

While Paraguay's evaluation was initiated before the GAO audit, the risk analysis was completed in 2018, after APHIS had addressed the GAO audit recommendations and incorporated them into policies and practices.

Several commenters stated that the risk analysis was based on outdated information on the potential for FMD exposure from Paraguayan beef. Two commenters pointed specifically to the site visits, which took place in 2008 and 2014, as being out of date. Another commenter stated that there are no official site visit reports from the APHIS in-country visits in 2008 and 2014. The commenter stated that APHIS should not proceed with this rulemaking until new site visits have occurred and an updated risk analysis is conducted based off the official site visit reports, and stakeholders are allowed time to review the results of the updated risk analysis.

We disagree with these assessments of the risk analysis. While the risk analysis included data from site visits to Paraguay in 2008 and 2014, it also included a review of more recent data provided by Paraguay, and APHIS periodically reviewed the risk profile of Paraguay after the risk analysis was drafted to determine whether the conclusions were still valid, with the last such review occurring in 2022. Additionally, for context, FMD has not been detected in Paraguay in more than 10 years. As noted in the risk assessment, the overall structure and resources of SENACSA have significantly increased and been strengthened in reaction to the FMD outbreak in 2012. Moreover, the incidence of FMD in South America has decreased steadily over the past

20 years, suggesting a continued decrease in risk of FMD incursion into Paraguay from neighboring countries. Currently, all countries in South America except Venezuela are recognized by WOAHP as FMD free, either with or without vaccination.

APHIS documented the findings of its 2008 and 2014 site visits in formal correspondence to Paraguay following the site visits, including requests for additional information and clarification of issues identified. Consistent with overall Agency policy, these government-to-government documents are maintained internally and not publicly posted. However, the totality of our evaluation and findings were documented in the risk analysis.

One commenter stated that 2021 data⁵ regarding FMD vaccination maintained by Paraguay was voluntarily submitted and incomplete. The commenter also provided a table of testing data for FMD that, the commenter contested, still showed the presence of FMD in Paraguay.

The data evaluated by the commenter was indeed incomplete and voluntarily submitted, but the site does not claim that this vaccination data is the data maintained by SENACSA to support claims of FMD freedom. To that end, it is worth noting, as we did previously, that FMD has not been detected in Paraguay in more than 10 years. In this regard, we note that the commenter misread the tables regarding testing for FMD. As we stated in the risk analysis that accompanied the proposed rule, samples in Paraguay are screened for FMD using an Enzyme Linked Immunosorbent Assay 3ABC Nonstructural Protein Antibody (ELISA) test; if they are reactive, they are sent for confirmatory testing using an Electroimmunotransfer Blot Assay (EITB) test. While several samples were reactive to the ELISA screening test, none were reactive to the confirmatory EITB test.

Moreover, it is also worth noting that, based on the dossier Paraguay submitted to WOAHP, WOAHP still considers Paraguay free of FMD with vaccination. Additionally, the

⁵ The commenter cited the following website containing the data:
<https://www.senacsa.gov.py/index.php/Temas-pecuarios/sanidad-animal/programas-sanitarios/fiebre-aftosa>. Please note that the page cited is in Spanish.

commenter appears to equate FMD freedom with vaccinating cattle for FMD, and to assume that our evaluation presumed vaccination as one of Paraguay's mitigation measures for FMD. This misunderstands our evaluation. Vaccination for FMD was not part of our mitigation structure, but rather why we considered mitigations for FMD risk to be warranted. A possible downtick in vaccination in Paraguay does not alter our mitigation strategy for beef from Paraguay.

One commenter stated that according to the risk analysis, most funding for Paraguay's FMD program comes from user fees, including fees from the movement of cattle, which means the success of the program is based on private sector support. The commenter expressed concern that APHIS has not taken into consideration the impact of economic downturns from the global pandemic that may limit Paraguay's overall capabilities. The commenter suggested that APHIS should re-evaluate the economic strength of the cattle and beef sector in Paraguay and review the FMD budget for the past 5 years to have a more accurate assessment of Paraguay's capabilities to fund efforts to combat and control an FMD outbreak.

In the proposed rule, APHIS proposed to apply numerous conditions to the importation of fresh beef from Paraguay that currently apply to fresh beef or ovine meat from specified regions that APHIS does not recognize as FMD free. These conditions are designed to mitigate the risk of introduction of FMD virus into the United States and protect America's livestock health, and have been demonstrated in the past to successfully address FMD risk. We have confidence that these mitigations will be effective in addressing the possible FMD risk associated with the importation of beef from Paraguay.

However, we do acknowledge the challenges FMD programs face worldwide, including the possible economic downturns cited by the commenter; while economic downturns may not always have animal health implications, in some instances they may. To that end, shipments of animal products are inspected for regulatory compliance at ports of entry and are subject to remedial measures, including destruction, if they are found to be noncompliant. Moreover, APHIS routinely monitors the animal health statuses of foreign regions for evidence that our

previous conclusions may no longer be germane, and adjusts import requirements as warranted if the import risk level changes. This process strengthens assurances that our import procedures continue to appropriately mitigate the risk of foreign animal disease introduction over time by maintaining a high level of vigilance and, if necessary, adjusting safeguards when new information or situations arise.

Some commenters expressed concerns with trusting our sanitary restrictions. One commenter stated that despite a 2-year ban issued by FSIS against JBS, a meat processing company in Brazil, after JBS shipped rotten, salmonella-ridden beef to the United States, JBS continued to export beef. The commenter stated that USDA's actions with JBS indicate that our sanitary restrictions are not absolute. Another commenter noted that Brazil has announced it will no longer vaccinate its cattle herd for FMD. The commenter further stated that "USDA's lack of response to Brazil's repeated offenses sends the message to neighboring countries that actions like that are permissible, even for countries with a history of FMD." The commenter expressed concern that Paraguay might follow suit and stop vaccinating its cattle for FMD.

The actions of FSIS are outside the scope of this rulemaking. However, meat products are inspected at ports of entry for compliance with APHIS requirements, and APHIS monitors the animal health status of foreign regions on an ongoing basis. Regarding vaccination, as stated in the proposed rule, FMD vaccination presents an FMD risk in terms of immunological response. Accordingly, the proposed rule was not predicated on Paraguay's vaccination regime but rather the results of its import risk analysis.

One of the above commenters stated that Brazil plays a leading role in Paraguay's beef industry, particularly in terms of ownership of their slaughterhouses. The commenter asked if APHIS evaluated slaughterhouses as part of our analysis.

APHIS did evaluate slaughterhouses as part of our analysis. The results of the APHIS evaluation indicate that Paraguay has effective animal health and animal disease emergency response systems in place.

One commenter noted political instability in Paraguay and asked if this had disrupted their sanitary systems.

We have no evidence that political instability has disrupted Paraguay's sanitary efforts; however, as noted above, we constantly monitor our trading partners for shifts in disease status.

A commenter noted a shift from grass-finished to grain-finished cattle in Paraguay and cited a USDA report in support of this assertion. The commenter suggested this shift could affect the conclusions of our risk assessment.

As the commenter noted, this shift is incremental and grass-fed beef still accounts for the majority of beef production in Paraguay, a fact that many commenters underscored. The article cited by the commenter also supports the gradual nature of this shift, noting that specific natural weather conditions in Paraguay had been a primary factor in the shift, as producers resorted to alternative feeds such as hay, forage, and grains to finish their cattle. The report suggests this shift was driven by a specific need, rather than indicative of an overall trend in production practices.

Finally, the manner in which cattle are finished in Paraguay also does not materially impact the conclusions of the risk analysis or the mitigation structure of the proposed rule; grain-finishing is not generally correlated with FMD risk. We likewise note that the mitigations of the proposed rule that are specifically intended to denature FMD or remove FMD risk, particularly the maturation and deboning processes, are similarly effective regardless of whether the beef is grass-fed or grain-finished.

Economic Comments

We received a number of comments regarding the Initial Regulatory Flexibility Analysis and Regulatory Impact Analysis (RIA) that accompanied the proposed rule. These comments are addressed within the RIA that accompanies this final rule.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this final rule on small entities. Copies of the full analysis are available on the Regulations.gov⁶ website (see footnote 6 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This final rule will allow importation of fresh beef from Paraguay into the United States under specified conditions. With few exceptions, APHIS' regulations in 9 CFR part 94 prohibit the importation of fresh (chilled or frozen) meat of ruminants or swine that originates in or transits a region where FMD is considered to exist. APHIS does not consider Paraguay as free of FMD because Paraguay vaccinates against FMD.

The United States is the world's largest beef producer, primarily of grain-fed beef for the domestic and export markets. Over the 5-year period, 2018 to 2022, the United States produced an annual average of about 12 million metric tons of beef, exported about 1.4 million metric tons, and imported about 1.4 million metric tons. Most U.S. beef imports are products from grass-fed cattle. These products are processed together with higher-fat trimmings from U.S. grain-fed beef to produce ground beef. Canada, Australia, New Zealand, and Mexico historically have been the largest sources of U.S. beef imports.

Paraguay's cattle industry is one of the country's major agricultural activities. Along with soybeans, beef is one of Paraguay's leading exports. Ongoing structural changes to the country's beef industry are occurring, as cattle ranching is displaced from traditional production areas by increased soybean acreage and grain is increasingly used to supplement beef cattle

⁶ To view the economic analysis, go to <https://www.regulations.gov/docket/APHIS-2018-0007/document>.

feeding regimes. About 65 percent of Paraguayan beef was exported over the 5 years, 2018-2022 (372,000 of 582,000 MT), a quantity equivalent to approximately 26 percent of U.S. fresh beef imports for the same period.

As a measure of possible impacts of fresh beef imports from Paraguay, we consider import volumes of 3,250 to 6,500 MT, that is, 5 to 10 percent of the Other Countries or Areas tariff-rate-quota of 65,005 MT. For each of the annual import levels, we modeled changes in U.S. consumption, production, and price, deriving annual consumer and producer welfare effects. The results of the analysis indicate that consumer gains of \$14 million to \$27 million would outweigh producer losses of \$12 million to \$24 million, yielding annual net social welfare gains of \$1.6 million to \$3 million. We also expect a portion of the beef imported from Paraguay will displace beef that would otherwise be imported from other countries.

Small entities in the United States are predominant among enterprises that would be affected by this rulemaking. They include beef and cattle producers, as well as feedlots and slaughter facilities. Of the 882,692 farms in the United States with cattle and calves, 711,827 sold cattle and calves, 729,046 were classified as beef cow farms, and 54,599 had milk cows. Based on these data and Small Business Administration standards, the majority of these entities are small.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the importation of fresh (chilled or frozen) beef from Paraguay under the conditions specified in this

final rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, APHIS has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov website.⁷ Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1620, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799-7039 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0487, have been submitted for approval to the Office of

⁷ To view the environmental assessment, go to <https://www.regulations.gov/docket/APHIS-2018-0007>.

Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the *Federal Register* providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this final rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851-2483.

List of Subjects in 9 CFR part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 1633, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. Amend § 94.29 as follows:

a. In the introductory text, by adding the words “fresh (chilled or frozen) beef from Paraguay;” after the word “Tocantins;”;

b. In paragraph (a)(1), by adding the words “or in Paraguay;” after the word “Brazil”;

- c. In paragraph (b), by adding the words “in Paraguay (for beef from Paraguay),” after the words “(for beef from Brazil),”; and
- d. By revising the OMB citation at the end of the section.

The revision reads as follows:

§ 94.29 Restrictions on importation of fresh (chilled or frozen) beef and ovine meat from specified regions.

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(Approved by the Office of Management and Budget under control numbers 0579-0372, 0579-0414, 0579-0428, 0579-0449, and 0579-0487)

Done in Washington, DC, this 3rd_{day} of November 2023.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

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